

S/N 10/600,118

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-------------|---|-----------------|--------------------|
| Applicant: | William W. Cimino | Examiner: | Laura A. Bouchelle |
| Serial No.: | 10/600,118 | Group Art Unit: | 3763 |
| Filed: | June 20, 2003 | Docket. No.: | 40206.19USU1 |
| Title: | PRECISION FLUID DELIVERY SYSTEM AND METHOD FOR SURGICAL PROCEDURES | | |

Electronically Filed March 11, 2011

SUPPLEMENTAL FILING

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed herewith is a signed declaration of Mr. Daniel S. Goldberger. The declaration was previously filed on February 22, 2011 without Mr. Goldberger's signature and without Mr. Goldberger's Curriculum Vitae in Exhibit A. The enclosed declaration includes Mr. Goldberger's signature and Mr. Goldberger's Curriculum Vitae in Exhibit A.

Respectfully submitted,

Dated: March 11, 2011



/René A. Pereyra/

René A. Pereyra, Reg. No. 45,800
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
303.357.1637

S/N 10/600,118

PATENT

CONE. NO. 9143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------|---|-----------------|--------------------|
| Applicant: | William W. Cimino | Examiner: | Laura A. Bouchelle |
| Serial No.: | 10/600,118 | Group Art Unit: | 3763 |
| Filed: | June 20, 2003 | Docket. No.: | 40206.19US01 |
| Title: | <u>"Precision Fluid Delivery System and Method for Surgical Procedures"</u> | | |

DECLARATION UNDER 37 C.F.R. § 1.132
BY DANIEL S. GOLDBERGER

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Daniel S. Goldberger, declare that:

1. I am the Chief Executive Officer of Sound Surgical Technologies LLC ("Sound Surgical") assignee of U.S. Patent Application Serial No. 10/600,118 (the "present application") identified above and the invention described therein. I have been CEO of Sound Surgical since April 2007.

2. I received a Bachelor of Science degree in mechanical engineering from the Massachusetts Institute of Technology, and a Master of Science degree in mechanical engineering from Stanford University.

3. I have been involved in the medical device field since 1979. Among other positions, in 1994 I co-founded Optiscan Biomedical Corporation. From 2001 to 2004, I was president of the Medical Group of OSI Systems (a NASDAQ traded company), including Spacelabs Medical, Dolphin Medical, and Osteometer. Immediately prior to joining Sound

Surgical, I was Chief Executive Officer of Glucon, Inc., a developer of glucose monitoring devices based on photoacoustic principles.

4. I am an inventor on more than 50 U.S. patents in the medical device field. I have basic understanding of the principles regarding the validity and infringement of U.S. patents. I have attached a copy of my Curriculum Vitae to this Declaration as Exhibit A.

5. I am generally familiar with the industry relating to cosmetic/aesthetic surgery including lipoplasty, Ultrasonic Assisted Lipoplasty (UAL), body contouring, and related procedures including breast enhancement and reduction. This knowledge has been obtained from my education and experience outlined above and specifically from my involvement in all facets of Sound Surgical's business including interaction with customers and potential customers, attendance at trade shows, conventions, and seminars. As a result of these activities, I have a working knowledge of the products available in these markets including those available from competitors of Sound Surgical.

6. I am aware that the present application is currently rejected by the United States Patent Office, and that this Declaration is being submitted in support of arguments against the obviousness of the invention claimed in the present application.

7. The invention claimed in the present application is embodied in a precision fluid management system (PFMS) sold as part of Sound Surgical's VASER system since 2004.

8. I have reviewed the Declaration of Dr. Mark Jewell, M.D., submitted in connection in the present patent application in support of arguments against the obviousness of the invention claimed in the present application. I find the statements made in Dr. Jewell's Declaration consistent with my knowledge and experience regarding equipment and procedures for precisely monitoring rapid fluid flow for aesthetic medical procedures. Simply stated, to the best of my knowledge, the device described and claimed in the present patent application is the first device available to the market that can precisely monitor rapid fluid flow for aesthetic medical procedures such as UAL procedures.

9. The only other commercial devices that I am aware of that purport to provide the capability of precisely monitoring rapid fluid flow for aesthetic medical procedures (i.e., the EZ Pump™ by Mentor and Tumescant Measuring Device by M.D. Resources referred to in paragraphs 10 and 11, respectively below) are “knock—offs” (i.e., copies) of the PFMS sold as part of Sound Surgical’s VASER system, which embodies the principles of the pending patent application. The Mentor device and the M.D. Resources device were both introduced to the market after Sound Surgical introduced its popular PFMS.

10. I have attached to this Declaration as Exhibit B product literature of the EZ Pump™ product. I have reviewed the literature and the EZ Pump™ product and believe that it includes all of the features of at least one apparatus claim in the present application and when used in practice for its intended purpose would utilize all of the features of at least one method claim in the present patent application.

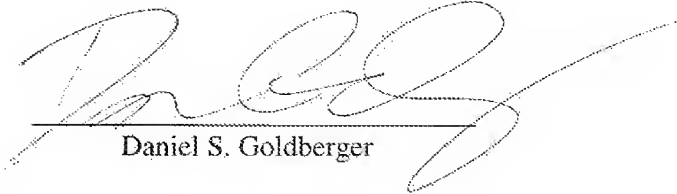
11. I have attached to this Declaration as Exhibit C product literature of the Tumescant Measuring Device product. I have reviewed the literature and the Tumescant Measuring Device product and believe that when used with the requisite pump it includes all of the features of at least one apparatus claim in the present application and when used in practice for its intended purpose would utilize all of the features of at least one method claim in the present patent application.

12. Other than Sound Surgical’s PFMS, and the copies mentioned above, I am unaware of any other system or method for rapidly and precisely delivering fluid in aesthetic medical procedures.

13. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code,

and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

February 22, 2011



Daniel S. Goldberger

S/N 10/600,118

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CONF. NO. 9143

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BY DANIEL S. GOLDBERGER

EXHIBIT A

CURRICULUM VITAE OF DANIEL S. GOLDBERGER

Daniel S. Goldberger

Chief Executive Officer

Mr. Goldberger brings more than 25 years of success leading medical device businesses.

Prior to joining Sound Surgical Technologies, Mr. Goldberger was chief executive officer of Glucon, Inc., a developer of glucose monitoring devices based on photoacoustic principles. From 2001 to 2004, he was president of the Medical Group of OSI Systems, Inc. (Nasdaq: OSIS). The Medical Group grew to exceed \$250 million under Mr. Goldberger's leadership, and included Spacelabs Medical, Dolphin Medical and Osteometer.

In 1994, Mr. Goldberger co-founded Optiscan Biomedical Corporation, a venture-backed project in the glucose monitoring field. He previously held general management positions with Ohmeda and Nellcor, both suppliers of critical care solutions.

Mr. Goldberger earned a BSME from the Massachusetts Institute of Technology and an MSME from Stanford University. He is an inventor on more than 50 U.S. patents in the medical device field.

Partial List of Patents on which Daniel S. Goldberger is an Inventor

7,608,042 Blood monitoring system

7,593,108 Method of determining analyte concentration in a sample using infrared transmission data

7,271,912 Method of determining analyte concentration in a sample using infrared transmission data

7,122,154 Apparatus for testing breath alcohol with discrimination between alveolar and upper respiratory tract alcohol

7,096,124 Method of determining an analyte concentration in a sample from an absorption spectrum

7,050,157 Reagent-less whole-blood glucose meter

7,009,180 Pathlength-independent methods for optically determining material composition

7,006,857 Method for determining analyte concentration using periodic temperature modulation and phase detection

6,959,211 Device for capturing thermal spectra from tissue

6,958,809 Reagent-less whole-blood glucose meter

6,944,486 Method and apparatus for determining analyte concentration using phase and magnitude detection of a radiation transfer function

6,931,328 Analyte detection system with software download capabilities

6,862,534 Method of determining an analyte concentration in a sample from an absorption spectrum

6,645,142 Glucose monitoring instrument having network connectivity

6,636,753 Solid-state non-invasive infrared absorption spectrometer for the generation and capture of thermal gradient spectra from living tissue

6,631,282 Device for isolating regions of living tissue

6,580,934 Method and apparatus for determining analyte concentration using phase and magnitude detection of a radiation transfer function

6,577,885 Method for determining analyte concentration using periodic temperature modulation and phase detection

6,556,850 Method for determining analyte concentration using periodic temperature modulation and phase detection

6,198,949 Solid-state non-invasive infrared absorption spectrometer for the generation and capture of thermal gradient spectra from living tissue

6,196,046 Devices and methods for calibration of a thermal gradient spectrometer

6,161,028 Method for determining analyte concentration using periodic temperature modulation and phase detection

6,095,986 Disposable anti-fog airway adapter

6,091,504 Method and apparatus for measuring gas concentration using a semiconductor laser

6,072,180 Non-invasive infrared absorption spectrometer for the generation and capture of thermal gradient spectra from living tissue

6,049,081 Subsurface thermal gradient spectrometry

6,025,597 Non-invasive infrared absorption spectrometer for measuring glucose or other constituents in a human or other body

5,932,877 High performance side stream infrared gas analyzer

5,900,632 Subsurface thermal gradient spectrometry

5,807,261 Noninvasive system for characterizing tissue in vivo

5,785,658 In vivo tissue analysis methods and apparatus

5,772,597 Surgical tool end effector

5,769,791 Tissue interrogating device and methods

5,762,609 Device and method for analysis of surgical tissue interventions

5,676,139 Spring clip probe housing

5,638,593 Method for manufacturing a heat-sealed neo-natal medical monitoring probe

5,615,672 Self-emission noninvasive infrared spectrophotometer with body temperature compensation

5,515,847 Self-emission noninvasive infrared spectrophotometer

5,460,182 Tissue penetrating apparatus and methods

5,387,122 Pulse oximeter probe connector

D355,032 Medical monitoring equipment probe connector

5,376,555 Method for testing breath alcohol with discrimination between alveolar and upper respiratory tract alcohol

5,313,941 Noninvasive pulsed infrared spectrophotometer

5,296,706 Shutterless mainstream discriminating anesthetic agent analyzer

5,282,473 Sidestream infrared gas analyzer requiring small sample volumes

5,281,817 Method of selecting an optical filter for a shutterless optically stabilized capnograph

D342,135 Airway adapter

5,249,576 Universal pulse oximeter probe

5,247,185 Regulated infrared source

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EXHIBIT B

LITERATURE:

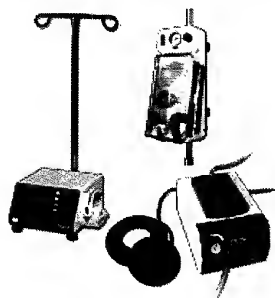
PRODUCT LITERATURE FOR THE EZ PUMP™ PRODUCT

The largest selection of Infiltration Systems known worldwide for convenience, reliability, and accuracy.

- EZ PUMP™
- PSI-TEC™ Infiltrator
- Big Bag 3000
- BP Cuff™

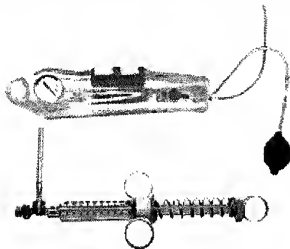
Infiltration Systems - Infiltrators

EZ PUMP™



| Catalog # | Description |
|-------------|--|
| EZ-PUMP | Peristaltic Infiltration/Irrigation Pump |
| BB3000 | Big Bag 3000 (500 cc - 3000 cc capacity) |
| PT-PINF-III | PSI-TEC III™ Infiltrator A compact system featuring easy set up and adjustable flow control. • Small footprint and ultra compact design • Powerful micro pump delivering open flow rate of 600 ml/minute. |
| BP CUFF | BP Cuff™ 1000 ml Unit Complete |

Infiltration Systems - Accessories



| Catalog # | Description | Quantity |
|-----------|---|----------|
| BP CUFF-G | Pressure Gauge 0-760 mm Hg | EA |
| BP CUFF-B | Squeeze Bulb, Male Luer Lock & 4-way Stopcock | EA |
| BP CUFF-E | Extension for 3-Liter Bag | EA |

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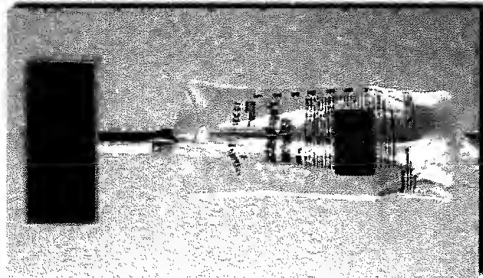
EXHIBIT C

LITERATURE:

PRODUCT LITERATURE FOR THE TUMESCENT MEASURING DEVICE PRODUCT



Tumescent Measuring Device



Quantity in Basket: none
 Code: TMD
 Price: \$650.00
 Shipping Weight: 10.00 pounds

Please call for quote:

Quantity: Add To Basket

Please call for quote.

With an innovative design, the TMD continues the M. D. Resource line of devices for tumescent procedures. Its convenient pole top mount delivers effortless measurement of total tumescent delivery. Weight lost from the hanging tumescent fluid bag is digitally displayed with +/- 1 ml accuracy.

The very low current circuitry enables the TMD to be ☐ piggy backed ☐ to our KPump or it can be used as a ☐ stand-alone ☐ device.

SPECIFICATIONS

Display ☐☐☐☐☐☐☐☐☐☐☐
 4-digit LCD with blue backlight 60 degree viewing window visible with 1 inch digits.
 Start Switch ☐☐☐☐☐☐☐☐☐☐
 Once for ☐ On ☐, once for ☐ Off ☐. Starts or restarts at 0 (zero).

Power□□□□□□□□ Supplied AC adapter provides 24 VDC @ 1 A. Operates with DC power supply of 8 to 40 volts @ 100 mA.

Hook□□□□□□□□. Stainless steel hook accommodates up to 3 saline bags.

Load Limit□□□□□□ Up to 4,000 ml (4 kg) maximum advised load.

Mounting□□□□□□□. Mounts on adjustable height pole with 7/8(.875)□ O.D.

Questions about ordering? ► [Contact Us](#)

23392 Connecticut Street Hayward, CA 94545 Call 1-800-MDEVICE Fax: 510.785.8182